



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

January 11, 2007

**WARNING LETTER NYK 2007-07**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Donald F. Doody  
Owner and Principal Operator  
Doody Farms, LLC  
5541 Large Road  
Auburn, New York 13021-9788

Dear Mr. Doody:

An inspection of your dairy operation located at 1939 Dougall Road, Fleming, New York, was conducted by a representative of the U.S. Food and Drug Administration (FDA) on October 24 – November 1, 2006. The inspection confirmed you offered a cow for sale for slaughter as food that was adulterated under sections 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] and 402(a)(4) [21 U.S.C. § 342(a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and its associated regulations on the Internet through links in FDA's web page at [www.fda.gov](http://www.fda.gov).

On or about February 6, 2006, you delivered for sale a dairy cow identified with your farm/ear tag 930 for slaughter as food to [REDACTED] where it was further identified with back tag [REDACTED]. On or about February 7, 2006, this cow was subsequently shipped to [REDACTED] where it was slaughtered. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from the animal identified the presence of 5.34 parts per million (ppm) sulfamethazine in liver tissue and 3.14 ppm sulfamethazine in muscle tissue. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in edible tissues of cattle, as codified in Title 21, Code of Federal Regulations, Section 556.670 (21 C.F.R. 556.670). The presence of this drug in these amounts in edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)].

Our investigation also found you hold animals under conditions so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drugs from edible tissues. For example, you failed to maintain treatment records, and you lacked an adequate inventory system for determining the quantities of drugs used to medicate your animals. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) [21 U.S.C. § 342(a)(4)] of the Act.

Doody Farms, LLC

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The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law.

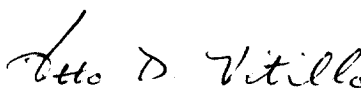
Additionally, you should be aware that sulfamethazine is not approved for use in lactating cattle as codified in 21 C.F.R. 520.2260b, and is prohibited from extralabel use in lactating dairy cattle as codified in 21 C.F.R. 530.41(a)(9). We have enclosed a copy of 21 C.F.R. Part 530, which contains the requirements for extralabel use of approved animal drugs and human drugs.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Compliance Officer Patricia A. Clark at the above address. If you have any questions about this letter, please contact Ms. Clark at the above address or by phone at (716) 551-4461, ext. 3168.

Sincerely,



Otto D. Vitillo  
District Director  
New York District

Enclosure:  
21 C.F.R. Part 530

Cc: [REDACTED] (redacted)

[REDACTED]

[REDACTED] (redacted)

[REDACTED]